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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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EXAMINER

SHEIKH, HUMERA N

ART UNIT

PAPER NUMBER

1615

DATE MAILED: 06/10/2002

9

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/899,026

Applicant(s)

STAMM ET AL.

Examiner

Humera N Sheikh

Art Unit

1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 April 2002 (paper no 8).
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 35-90 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 35-90 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☒ Certified copies of the priority documents have been received in Application No. 09/005,128.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Status of the Application

Acknowledgement is made of the request for extension of time (1 month), the Amendment and the Terminal Disclaimer, all filed 01/23/02 and the supplemental Amendment and formal drawings filed 04/02/02.

In view of the new references that have been brought to the attention of the examiner in an updated search, it is necessary to continue prosecution on claims previously indicated as being allowable. The indication of allowance of claims 35, 46-51, 53-56 and 52 is withdrawn and a new office action follows.

Claims 35-90 are pending. Claims 35-90 are rejected.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 35, 39, 40, 41, 44, 52, 59, 61 and 77-80 are rejected under 35 U.S.C. 102(b) as being anticipated by Boyer (US Pat. No. 4, 800,079).

Boyer discloses a fenofibrate composition comprising granules, wherein the granules comprise an inert core with hydrosoluble carrier particles (lactose), a hydrophilic polymer (polyvinylpyrrolidone) and a fenofibrate microparticle layer, wherein

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the fenofibrate particles have a particle size of not greater than 30 microns (see entire reference).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 35-42, 44, 46-48, 50, 54-62, 65-70, 73-80, 86, 87 and 89-90 are rejected under 35 U.S.C. 103(a) as being unpatentable over Boyer (US Pat. No. 4, 800,079).

Boyer teaches a fenofibrate composition comprising granules, wherein the granules comprise an inert core with hydrosoluble carrier particles (lactose), a hydrophilic polymer (polyvinylpyrrolidone) and a fenofibrate microparticle layer, wherein the fenofibrate particles have a particle size of not greater than 30 microns (see reference columns 2-4).

Boyer, while disclosing a fenofibrate composition with granules comprising fenofibrate, a hydrophilic polymer (polyvinylpyrrolidone) and a hydrosoluble carrier (lactose), does not explicitly teach all the exact instantly claimed weight ratios and percentages. It would have been obvious to one of ordinary skill in the art at the time the invention was made that suitable ratios and percentages could be determined through routine or manipulative experimentation. In addition, no criticality is seen in the

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instantly claimed weight ratios and percentages since Boyer teaches the same claimed ingredients in similar amounts, thereby allowing for the same properties.

Regarding claims 42 and 48, it is deemed obvious to one of ordinary skill in the pharmaceutical art to formulate a tablet form using the compression of granules.

Claims 43, 45, 49, 51, 53, 63, 64, 71, 72, 81-85 and 88 are rejected under 35 U.S.C. 103(a) as being unpatentable over Boyer (US Pat. No. 4, 800,079) in view of Curtet *et al.* (US Pat. No. 4, 895,726).

Boyer teaches a fenofibrate composition comprising granules, wherein the granules comprise an inert core with hydrosoluble carrier particles (lactose), a hydrophilic polymer (polyvinylpyrrolidone) and a fenofibrate microparticle layer, wherein the fenofibrate particles have a particle size of not greater than 30 microns (see reference columns 2-4).

Boyer while disclosing a fenofibrate composition with granules comprising fenofibrate, a hydrophilic polymer (polyvinylpyrrolidone) and a hydrosoluble carrier (lactose), does not explicitly teach a surfactant in the fenofibrate composition.

Curtet *et al.* teach a fenofibrate composition comprising micronized fenofibrate in combination with a surfactant (sodium-lauryl sulfate) (see reference columns 1-6). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to formulate a fenofibrate composition co-micronized with a surfactant (sodium lauryl-sulfate), which makes it possible to improve the absorption

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and consequently the bioavailability of the fenofibrate to a greater extent. The expected result would be an improved and highly effective fenofibrate composition.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Humera Sheikh whose telephone number is (703) 308-4429. The examiner can normally be reached on Monday through Friday from 7:00A.M. to 4:30P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page, can be reached on (703) 308-2927. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
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